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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/528,989	03/20/00	VOGEL, T	

HM12/0427

020582
PENNIE & EDMONDS LLP
1667 K STREET NW
SUITE 1000
WASHINGTON DC 20006

EXAMINER	
WELLS, L	

ART UNIT	PAPER NUMBER
1615	9

DATE MAILED: 04/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No.	Applicant(s)	
	09/528,989	VOGEL ET AL.	
	Examiner	Art Unit	
	Lauren Q Wells	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-51 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-51 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5-8 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09528990 and copending Application No. 09263773. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed towards analogous cell augmentation compositions comprising biocompatible, swellable, hydrophilic, non-toxic and substantially spherical microspheres and a biocompatible carrier, wherein said microspheres swell to a predetermined size after injection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 recites the limitation "the salt" in line 1 of claim 34. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-4, 6-8, 13, 21-22, 26, 31-33, 38, and 45-50 rejected under 35 U.S.C. 102(b) as being anticipated by Rhee et al. (5,550,187).

Rhee et al. teach a method of preparing crosslinked biomaterial compositions for use in tissue augmentation. Water and phosphate buffered saline are disclosed as aqueous carriers for the augmentation material. 27 gauge or smaller needles are disclosed as the needles used for injecting the composition. Polyethylene glycol is disclosed as the crosslinking agent, which meets claim 12. A kit is disclosed. See Col. 2, line 54-Col. 8, line 1; Col. 9, line 32-Col. 14, line 25; Col. 15, line 26-Col. 24, line 45.

Claims 1-4, 6-8, 13, 21, 22, 26 31-33, 38-39 and 42-46 rejected under 35 U.S.C. 102(e) as being anticipated by Hubbard et al. (5,922,025).

Hubbard et al. teach a spherical injectable soft tissue augmentation material that is suspended in a biocompatible resorbable fluid lubricant and wherein the composition is injectable through needles of about 18-26 gauge, which meets claim 1. Preferred embodiments of the lubricant are disclosed as aqueous glycerin and sodium carboxymethylcellulose, which meets claims 4, 7, 8. The augmentation material is disclosed for use in the vocal cords and the sphincter of the bladder. Autogenous tissue growth is disclosed as occurring into the matrix provided by the augmentation material. See Col. 4, line 10-Col. 5, line 65; Col. 7, line 3-Col. 16, line 62.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13, 17-18, 21-26, 31-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbard et al. or Rhee et al. in view of Boschetti et al. (5,648,100) and Tomoko (JP06056676).

Rhee et al. fails to teach emulsions, contrast agents, acylamino-e-propion-amido-3-triiodo-2,4,6-benzoic acid, preferred embodiments of the microspheres, therapeutic agents, radiopacifying agents, and contrast mediums (see above discussion).

Hubbard et al. fails to teach emulsions, contrast agents, acrylamino-e-propion-amido-3-triiodo-2,4,6-benzoic acid, preferred embodiments of the microspheres, therapeutic agents, radiopacifying agents, contrast mediums, and kits.

Boschetti et al. teach microspheres useful for therapeutic vascular occlusions and injectable solutions containing the same. Disclosed are microspheres comprising, in a copolymerized form, hydrophilic acrylic monomers, coated with cell adhesion promoters. Acrylamides, methacrylamides, and hydroxymethylmethacrylates are disclosed as hydrophilic acrylic monomers having a cationic charge. These microspheres are disclosed as further comprising marking agents, such as dyes, imaging agents, and contrasts agents. Acrylamino-3-propion-amido-3-triiodo-2,4,6-benzoic acid is disclosed as a marking agent. A method of tissue bulking is disclosed. See Col. 1, line 58-Col. 4, line 37; Col. 7, line 51-Col. 8, line 67.

Hori teaches a suspension for blocking blood vessels. The suspension is obtained by suspending high water absorbing resin granules chosen from the group consisting of polymers of sodium acrylate, polymers of sodium acrylate and vinyl alcohol, copolymers of vinyl acetate and acrylic acid ester, copolymers of vinyl acetate and methyl maleate, crosslinked copolymers of isobutylene-maleic anhydride, graft copolymers of starch-acrylonitrile, crosslinked sodium polyacrylate, and crosslinked polyethylene oxide, in an oily contrast medium (an emulsion). See entire abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the compositions of Rhee et al. or Hubbard et al. by adding a marking agent to the composition and obtain a microsphere that is detectable in vivo because a) Boschetti et al. teach such injectable solutions as making it possible to improve the efficacy of occlusion and to adapt treatment to the diameter and nature of the vessel to be embolized. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the compositions of Rhee et al. or Hubbard et al. by substituting the water absorbing resin granules of Tomoko or the microspheres comprising hydrophilic acrylic monomers of Boschetti et al., for the microspheres of Rhee et al. or Hubbard et al. because a) Tomoko teaches the granules as increasing their diameter 4.5 fold to act as blocking substances; b) Boschetti et al. teach that the hydrophilic character of the acrylic copolymer enables the microspheres to be placed in suspension in the form of sterile and pyrogenic injectable solutions, without the formation of aggregates and adhesion to the walls of the syringe/needle.

Claims 1-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhee et al. or Hubbard et al. in view of Boschetti et al. and Tomoko, in further view of Vacanti et al. (5,855,610).

Rhee et al. fail to teach autologous cells and antiinflammatories (see above disclosure).

Hubbard et al. fail to teach autologous cells added prior to injection and antiinflammatories (see above disclosure).

Boschetti et al. and Tomoko et al. are disclosed as discussed above.

Vacanti et al. teach a cell-matrix structure comprising a fibrous matrix seeded with dissociated human cells. Preferable cells disclosed are autologous cells, adipocytes (fat cells),

fibroblast cells (epidermal cells), and muscle cells. Bioactive molecules, such as antiinflammatores, are disclosed as additives that can be incorporated into microspheres which are suspended with the cells or attached to or incorporated within the matrix.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Rhee et al. by adding the cells of Vacanti et al. and obtain a composition comprising microspheres and cells because a) Vacanti et al. teach the cell-matrix for the augmentation of flexible, strong connective tissue; b) Rhee et al. teach injecting the composition in soft tissue sites in need of augmentation. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made have modified the composition of Hubbard et al. by adding the autologous cells of Vacanti et al. prior to injecting the composition to obtain an ex vivo composition comprising microspheres and autologous cells because a) Hubbard et al. and Vacanti et al. teach the in vivo growth of autologous cells as resulting in augmentation; b) Vacanti et al. teach the matrix as functioning as a cell delivery system that enables the organized transplantation of large numbers of cells into the body.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L Dudash can be reached on (703) 308-2328. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
April 11, 2001

4/10/01

DAMERON L. JONES
PRIMARY EXAMINER